IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, and GLOBAL LIFE SCIENCES SOLUTIONS USA, LLC,	)	[redacted]
Plaintiffs,	)	**Redacted - Public Version**
v.	)	C.A. No. 18-1899-CFC-SRF
BIO-RAD LABORATORIES, INC.,	)	**CONSOLIDATED**
Defendant.	)	

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO EXCLUDE EXPERT OPINIONS OF DR. BRUCE GALE AND IN SUPPORT OF THEIR MOTION TO EXCLUDE EXPERT OPINIONS OF DR. THOMAS KEARL

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I. THE COURT SHOULD EXCLUDE CERTAIN OPINIONS OF DR. BRUCE GALE

Plaintiffs demonstrated in their Opening Brief that certain opinions of Bio-Rad's expert Dr. Bruce Gale should be excluded as unreliable. Nothing in Bio-Rad's response compels a different conclusion.

A. Dr. Gale's Opinions Based Upon Improper Claim Construction Should Be Excluded

1. "Fluidics" And "Non-Fluidics" Sections

Dr. Gale wrongly provided extensive analysis of the specification and file history to reinterpret claim terms, including "fluidics section" and "non-fluidics section." (D.I. 173 at 7-8.) Bio-Rad argues that Dr. Gale's constructions were "consistent" with how the Court "already properly narrowed the scope of the claims." (D.I. 209 at 12.) If true, there was no reason for Dr. Gale to offer his views of the claim terms in view of the specification and file history or to arrive at his own interpretation, as he testified that he did. (*See* D.I. 173 at 3-5.) He simply chose to ignore the Court's construction, as well as the Court's statements that allow electronics to be in "other sections" in the claimed fluid handling units other than a single internal non-fluidics section. (D.I. 174, Ex. 3 at 97:16-25, 103:8-13.)

Bio-Rad's only support for its assertion that "Dr. Gale's non-infringement opinions are fully consistent with these claim constructions" is that Dr. Gale says so. (D.I. 209 at 10.) Bio-Rad fails to cite any portion of Dr. Gale's report where he

applies the Court's construction, and ignores the instances where Dr. Gale explicitly criticizes the Court's construction and reached a different conclusion about the meaning of claim terms based upon his consideration of the specification and file history. (*Compare* D.I. 174, Ex. 2 ¶44 *with* Ex. 3 at 103:8-11.)

Dr. Gale's discussion of the intrinsic record was offered solely to import additional requirements beyond the Court's construction. Any such analysis, and his non-infringement opinions based thereon, are unreliable.

2. "Panel Member" and "Independently Perform Operations"

Dr. Gale again improperly relies on the specification and/or file history to narrow the ***scope*** of these terms. (*See* D.I. 173 at 7-9.) Bio-Rad does not really argue otherwise; instead suggesting it was appropriate for Dr. Gale to construe claim terms post-*Markman* based upon his interpretation of the intrinsic record. (*See, e.g.*, D.I. 209 at 14.) Bio-Rad fails to explain how Dr. Gale's opinions are not improper claim constructions that usurp the role of the Court. *See NobelBiz, Inc. v. Glob. Connect, L.L.C.*, 701 F. App'x 994, 997 (Fed. Cir. 2017) ("Allowing the experts to make arguments to the jury about claim scope was erroneous.").[1]

Bio-Rad does not dispute Cytiva's showing that Dr. Gale's opinions on "panel

[1] Bio-Rad's reliance on *Wisconsin Alumni Research Found. v. Apple Inc.*, 905 F.3d 1341, 1348 (Fed. Cir. 2018) to support Dr. Gale's use of file history is misplaced. (D.I. 209 at 13.) That case addresses only ***the Court's*** determination of the plain and ordinary meaning of a term.

member" "limit[] the term to exclude structures that include integrated electronics" (D.I. 173 at 7), arguing that "it is Plaintiff that offers a contorted interpretation." (D.I. 209 at 14.) Neither Cytiva nor Dr. Wereley, however, have offered an "interpretation" of the term. For "independently perform operations in response to instructions over a BUS," Bio-Rad confirms that Dr. Gale relied on an embodiment in the specification to arrive at his construction. (*See* D.I. 209 at 16.) For both terms, Bio-Rad fails to explain why Dr. Gale's opinions are *not* improper constructions.

Bio-Rad's cases do not support permitting an expert to use the file history to opine on the plain and ordinary meaning. In *Level 3 Commc'ns, LLC v. Limelight Networks, Inc.*, No. 2:07-cv589, 2009 WL 10689350 at *5-6 (E.D. Va. June 23, 2009), the court found no error in use of the prosecution history at trial because the plaintiff did not timely object since it raised the issue ***after*** trial. In *GPNE Corp. v. Apple Inc.*, 108 F. Supp. 3d 839, 856 (N.D. Cal. 2015), the prosecution history was not used to construe a term, as even Bio-Rad admits. (D.I. 209 at 15.)

B. Dr. Gale's Opinions Regarding The 2016 Experiments Should Be Excluded

In its response, Bio-Rad not only continues to misrepresent Dr. Gale's involvement in the 2016 Experiments (as discussed in Cytiva's Opening Brief), but presents additional misrepresentations. None of Bio-Rad's arguments, as noted below, justify admission of Dr. Gale's opinions.

1. The 2016 Experiments

To give context for the disputed issues regarding the 2040 System and the 2016 Experiments, Bio-Rad makes staggering mischaracterizations. Bio-Rad falsely asserts that "the PTAB ruled that the manual for the 2040 System invalidated ***all*** of the claims of Plaintiffs' predecessor patent" and "the claims at that time did ***not*** include the term 'liquid chromatography'—but Plaintiff added that limitation to obtain the patents at issue in this case." (D.I. 209 at 4-5 (emphasis added).) Plaintiffs' '718 Patent, the patents-in-suit's parent, had several originally-issued claims reciting liquid chromatography systems (claims 11 and 16-18). (D.I. 221-1, Ex. 220 at 10:5-52.) The PTAB determined that Bio-Rad failed to make a threshold showing of unpatentability of those and other claims in view of the 2040 System. (*Id.*, Ex. 207 at 27-28.) Ultimately, the PTAB only found claims 1-3 and 5 of the '718 Patent unpatentable—not "all" claims. (D.I. 210, Ex. D at 33.)

Bio-Rad next overstates Dr. Gale's involvement in the 2016 Experiments,[2] stating that ***he*** "videotaped" or "recorded" the experiments, a claim that Dr. Gale also made in his report and declaration to the Court. (D.I. 209 at 1, 5; D.I. 174, Ex. 4 ¶299; D.I. 183 at 7; D.I. 186 ¶8.) This is baseless. Deposition testimony from both

[2] Cytiva does not seek exclusion of either "evidence of the 2040 System" (D.I. 209 at 1, 4) or Dr. Gale's (incorrect) opinion that "the 2040 System invalidates all of the asserted claims." (*Id*. at 6). Cytiva seeks to exclude ***only*** Dr. Gale's opinions relating to the 2016 Experiments.

Dr. Gale and Dr. Petersen confirms that Dr. Gale did not record the experiments and, in fact, Dr. Gale was not even certain which portions of the testing he was present. (D.I. 174, Ex. 7 at 99:12-100:8, 46:17-47:17; *Id.*, Ex. 1 at 107:4-12, 110:13-22.)

Ultimately, Bio-Rad's argument that Dr. Gale's purported oversight deems his opinions reliable is flawed because the opinions are replete with assertions directed to the central issue of whether a POSITA would have been motivated or able to devise a plan, program, and use the 2040 system as in the 2016 Experiments, purportedly to perform liquid chromatography. Yet, Dr. Gale is in no position to make reliable assertions on these issues because he does not know—even today—the full extent of time and effort involved in the 2016 Experiments. (*See* D.I. 174, Ex. 1 at 107:4-12, 113:8-114:9.)

Nothing in Bio-Rad's opposition shows that Dr. Gale has a reliable basis for his opinions. For example, Bio-Rad wrongly asserts that "[t]he Test Report…describes exactly the menu choices to program the device." (D.I. 209 at 6.) The Test Report does not describe the menu choices, but merely states that "[a]ll the programming was performed on the instrument using the built-in keypad and function buttons." (D.I. 210-1, Ex. J at 1.) Indeed, the exact work performed is unknown because the lab notebook containing the relevant programming

information was lost and Dr. Gale never reviewed it. (D.I. 173 at 11; D.I. 174, Ex. 1 at 209:6-210:1.)[3]

Bio-Rad's cited cases fail to show that an expert may offer opinions where there are gaping holes in the expert's knowledge base of testing. In *In re Gabapentin Patent Litigation*, No. 00-CV-2931, 2011 WL 12516763, at *11 (D.N.J. Apr. 8, 2011), the Court permitted testimony because, *inter alia*, the expert was "familiar with the [scientific testing] procedures and designs the quality controls used in these tests." Here, Dr. Gale acknowledged that he lacks firsthand knowledge of the extent of the work and programming necessary to conduct the experiment. (D.I. 174, Ex. 1 at 107:4-12; *id.* Ex. 7 at 99:12-100:8, 46:17-47:17.)

Eli Lilly and *Cryovac* are similarly inapposite because in both, the expert relied on research, rather than the speculation that Dr. Gale relies on here. *Eli Lilly & Co. v. Actavis Elizabeth LLC*, No. 07-CV-3770 (DMC), 2010 WL 11570123, at *3 (D.N.J. May 13, 2010); *Cryovac Inc. v. Pechiney Plastic Packaging, Inc.*, 430 F. Supp. 2d 346, 363 (D. Del. 2006).

[3] Bio-Rad's argument that Dr. Gale's knowledge of the notes and programming necessary for the 2016 Experiments would not affect the outcome of the experiment (D.I. 209 at 6 n.3), is irrelevant. Dr. Gale opines not only about the outcome, but also whether a POSITA could have "readily programmed" the experiments. (D.I. 174, Ex. 6, ¶¶40, 42.) Thus, his opinions necessarily rely on information he simply does not and could not know.

Finally, Bio-Rad fails to distinguish *XpertUniverse, Inc. v. Cisco Sys., Inc.*, C.A. No. 09-157-RGA, 2013 WL 865974, at *2 (D. Del. Mar. 7, 2013). Bio-Rad argues that testimony was excluded there because the expert "did not examine key documents or operations" (D.I. 209 at 8), but that is exactly what happened here. (D.I. 174, Ex. 1 at 209:6-210:1; D.I. 173 at 11.)[4]

2. Dr. Gale's Parroting Of Inadmissible Hearsay

In response to Cytiva's showing that Dr. Gale improperly parroted the opinions of Bio-Rad employee Katie Schaefer, Bio-Rad argues that an expert may permissibly rely on hearsay. (D.I. 209 at 8-9.) Bio-Rad made no attempt, however, to distinguish Cytiva's caselaw on this point.

Bio-Rad also incorrectly argues that Dr. Wereley "agrees" with Dr. Gale about the time necessary to work with a new machine—the information it states Ms. Schaefer provided to Dr. Gale—which purportedly provides a basis for admission. (*Id.* at 9.) Dr. Wereley merely stated that "there are always calculations required when you're doing…engineering measurements and things like that." (D.I. 210-1, Ex. K at 15:13-16.) This is nowhere close to Dr. Wereley's opinions

[4] Bio-Rad's attempt to distinguish *Callaway Golf Co. v. Acushnet Co.*, C.A. No. 06-91-SLR, 2007 WL 4165401 (D. Del. Nov. 20, 2007) also fails. Bio-Rad claims the *Callaway* expert had no supervisory role, unlike Dr. Gale. (D.I. 209 at 8.) The *Callaway* expert had more firsthand knowledge of the testing than Dr. Gale because the *Callaway* expert actually observed the testing. *Callaway*, 2007 WL 4165401, at *1.

regarding the extensive effort likely required for the 2016 Experiments (D.I. 221-24, Ex. A ¶¶332-50), and does not show that such effort would have been the same if using the already-programmed NGC systems.

II. THE COURT SHOULD EXCLUDE DR. KEARL'S OPINIONS BASED ON LICENSES WITH NO TECHNICAL COMPARABILITY

Bio-Rad concedes that it made ***no*** showing of technical comparability for [redacted] licenses Dr. Kearl relies on for his opinions. (D.I. 209 at 19 ("Neither expert contends the licenses other than the [redacted] discussed by [the experts] are technologically comparable.").) Notwithstanding this concession, which should end the argument as to the impropriety of these licenses, Bio-Rad still proffers several purported reasons why exclusion is inappropriate, none of which are availing.

First, Bio-Rad contends Dr. Kearl's "limited discussion" of the [redacted] licenses is permissible because the licenses "are reflective of industry practice" and "consistent with the [redacted] license agreements that are comparable." (*Id.* at 19, 20.) Neither of the cases relied by Bio-Rad for this argument, however, involved an examination of whether it was proper for a damages expert to rely on a license for which no showing of technical comparability was made.[5]

[5] *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1553 (Fed. Cir. 1983), involved an appeal from a final judgment, and *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354 (Fed. Cir. 1998), involved cross-appeals from post-trial motions. All of the cases cited by Plaintiffs in their Opening Brief involved the issue presented here of excluding licenses with no technical comparability. (D.I. 173 at 18-19.)

Second, Bio-Rad's argument that "Dr. Kearl's opinions demonstrate that the agreements he relies on are not 'radically different' from the hypothetical agreement he proffers or from the [redacted] comparable agreements" (*id.* at 20) is just attorney argument—since no technical comparability has been established, there is no basis to claim the [redacted] licenses are not "radically different," which is precisely why they should be excluded.

Finally, Bio-Rad's argument that Dr. Kearl can rely on the royalty rates from the [redacted] licenses because his "analysis does not use the agreements to ***establish*** a rate" (*id.* at 21 (emphasis in original)), ignores precedent from courts within this district and elsewhere that have prohibited relying on a non-comparable license for ***any*** purpose. *See, e.g.*, *M2M Sol. LLC v. Enfora, Inc.*, 167 F. Supp. 3d 665, 678 (D. Del. 2016);[6] *I/P Engine, Inc. v. AOL Inc.*, No. 2:11-cv512, 2012 WL 12068846, at *2 (E.D. Va. 2012). Bio-Rad cites no decision from any court supporting its argument that Dr. Kearl's reliance on non-comparable agreements is appropriate.

[6] Bio-Rad distinguishes *Enfora* by falsely claiming that "Dr. Kearl's 'sanity check' relies on the [redacted] ***comparable*** agreements." (D.I. 209 at 20 (emphasis added).) In fact, Dr. Kearl testified that he is relying on the rates from all licenses (including the [redacted] lacking technical comparability) as a "reasonableness check." (D.I. 174, Ex. 11 at 209:1-14.)

CONCLUSION

For the reasons provided above and in their Opening Brief, the Court should exclude the opinions and testimony of Bio-Rad's experts.

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CERTIFICATE OF COMPLIANCE

Pursuant to the Court's November 6, 2019 Standing Order, I hereby confirm that this brief complies with the type and number limitations set forth in the Standing Order. I certify that this document contains 2,213 words, which were counted using the word count feature in Microsoft Word, in 14-point Times New Roman font. The word count does not include the cover page, table of contents and authorities, or the counsel blocks font. The total number of words in all of Plaintiffs' reply case-dispositive and *Daubert* briefs is less than 6,250 words, calculated in the above manner.

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